

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kathleen FRESON et al.	Confirmation No.:	8603
Serial No.:	10/542,238	Art Unit:	1644
371(c) Date:	July 15, 2005	Examiner:	Michael E. SZPERKA
Patent No.:	7,615,219	Customer No.:	21559
Issued:	November 10, 2009		
Title:	INHIBITION OF PACAP SIGNALLING FOR THE PREVENTION AND TREATMENT OF THROMBOCYTOPENIA		

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

In response to the Determination of Patent Term Adjustment under 35 U.S.C. § 154(b) set forth in the Issue Notification mailed in connection with the above-captioned patent application on October 21, 2009, and as set forth on the cover of U.S. Patent No. 7,615,219 (“the ‘219 patent”), issued November 10, 2009, Applicants hereby request reconsideration of the patent term adjustment. Applicants submit that the current patent term adjustment should be 782 days, not 391 days as shown in the Patent Term Adjustment History on the PAIR system (Exhibit A).

Background Law and Rules

35 U.S.C. § 154(b)(1)(A) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the Patent and Trademark Office to-

(i) provide at least one of the notifications under section 132 of this title or a notice of allowance under section 151 of this title not later than 14 months after-

the date on which an application was filed under section 111(a) of this title; or

the date on which an international application fulfilled the requirements of section 371 of this title;

(ii) respond to a reply under section 132, or to an appeal taken under section 134, within 4 months after the date on which the reply was filed or the appeal was taken;

\* \* \*

the term of the patent shall be extended 1 day for each day after the end of the period specified in clause (i), (ii), (iii), or (iv), as the case may be, until the action described in such clause is taken.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(a), and 1.703(a). Applicants refer to Office delay under 35 U.S.C. § 154(b)(1)(A), and the corresponding rules, as “A delay.”

35 U.S.C. § 154(b)(1)(B) states:

Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application in the United States, not including-

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

\* \* \*

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

Corresponding provisions are found in 37 C.F.R. §§ 1.702(b) and 1.703(b). Applicants refer to Office delay under 35 U.S.C. § 154(b)(1)(B), and the corresponding rules, as “B delay.”

35 U.S.C. § 154(b)(2)(A) states (emphasis added):

**To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap,** the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

A corresponding provision is found in 37 C.F.R. § 1.703(f).

The Office has explained its interpretation of the “overlap” provisions of 35 U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f) as follows (emphasis added):

[T]he Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. 154(b)(1)(B), **the entire period during which the application was pending before the Office** (except for periods excluded under 35 U.S.C. 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, **is the relevant period under 35 U.S.C. 154 (b)(1)(B) in determining whether periods of delay “overlap” under 35 U.S.C. 154(b)(2)(A).**

Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office

Interpretation of 35 U.S.C. 154(b)(2)(A), 69 Fed. Reg. 34283, 34283 (Jun. 21, 2004).

However, the Office’s interpretation was recently rejected by the U.S. District Court for the District of Columbia, which stated (emphasis added in bold; original emphasis in italics):

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether “periods of delay attributable to grounds specified in paragraph (1) overlap.” **The only way that periods of time can**

**“overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another, they do not overlap, and § 154(b)(2)(A) does not limit the extension to one day.** Recognizing this, the PTO defends its interpretation as essentially running the “period of delay” under sub-section (B) from the filing date of the patent application, such that a period of “B delay” *always overlaps* with any periods of “A delay” for the purposes of applying § 154(b)(2)(A).

**The problem with the PTO’s construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies “if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years.” (Emphasis added.) “B delay” begins when the PTO has failed to issue a patent within three years, not before.**

Wyeth v. Dudas, 580 F.Supp.2d 138, 141-142 (D.C.D.C., 2008).

Accordingly, Applicants submit that, where A delay occurs entirely before the three-year date, and thus does not overlap the period of B delay, the periods of A delay and B delay are not to be considered overlapping under § 154(b)(2)(A), but rather must be added together to determine the overall Office delay.

### The ‘219 Patent

The ‘219 patent entered the U.S. national stage under 35 U.S.C. § 371 on July 15, 2005, and a Restriction Requirement was mailed by the Office on October 11, 2007, which is 391 days past the 14-month date of September 15, 2006, consistent with the determination shown in Exhibit A. As such, Applicants agree that the Office A delay is 391 days.

Applicants also agree with the Office's determination of 92 days of Applicant A delay associated with Applicant's failure to reply to the July 9, 2008 Office Action within the three month period required by 37 C.F.R. § 1.704.

The Office calculated the period of B delay to be 483 days, as shown in Exhibit A. Under 37 C.F.R. §§ 1.702(b) and 1.703(b), the time interval between the date that is three years from national stage commencement and the issue date counts as B delay. In this case, the three-year date was July 15, 2008. The patent issued on November 10, 2009, which is 483 days past the three-year date of July 15, 2008. Accordingly, Applicants agree that the period of B delay is 483 days as determined by the Office.

As is discussed above, when the periods of A delay and B delay do not overlap, Applicants are entitled to both periods of delay. Here, the period of Office A delay terminated on October 11, 2007 with the mailing of the Restriction Requirement, while the period of B delay began on July 15, 2008. Accordingly, the periods of Office A delay and B delay are non-overlapping, and Applicants are entitled, under U.S.C. § 154(b)(2)(A) and 37 C.F.R. § 1.703(f), to the sum of these periods in the patent term adjustment calculation.

Applicants conclude that the Office delay associated with the '219 patent is 391 days (A delay) + 483 days (B delay) = 874 days, while the Applicant delay is 92 days. Thus, the '219 patent is entitled to a total of  $874 - 92 = 782$  days of patent term adjustment under 37 C.F.R. § 1.703. Applicants request that the patent term adjustment determination be corrected accordingly.

The present patent is not subject to a Terminal Disclaimer.

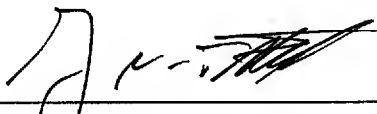
CONCLUSION

Applicants submit that the current patent term adjustment should be 782 days and hereby request reconsideration of the patent term adjustment.

Transmitted herewith is \$200.00 in payment of the fee set forth in 37 C.F.R. § 1.18(e). If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 6 January 2010

  
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Jan N. Tittel  
Reg. No. 52,290

Clark & Elbing LLP  
101 Federal Street  
Boston, MA 02110  
Telephone: 617-428-0200  
Facsimile: 617-428-7045

## Exhibit A

10/542,238	INHIBITION OF PACAP SIGNALLING FOR THE PREVENTION AND TREATMENT OF THROMBOCYTOPENIA	12-30-2009::10:42:32
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**Patent Term Adjustments**

Patent Term Adjustment (PTA) for Application Number: 10/542,238

Filing or 371(c) Date:	07-15-2005	USPTO Delay (PTO) Delay (days):	483
Issue Date of Patent:	11-10-2009	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	92
Post-Issue Petitions (days):	+0	Total PTA (days):	391
USPTO Adjustment(days):	+0	Explanation Of Calculations	

**Patent Term Adjustment History**

Date	Contents Description	PTO(Days)	APPL(Days)
10-21-2009	PTA 36 Months	92	
11-10-2009	Patent Issue Date Used in PTA Calculation		
10-05-2009	Dispatch to FDC	⬆	
10-05-2009	Application Is Considered Ready for Issue	⬆	
09-25-2009	Issue Fee Payment Verified	⬆	
09-25-2009	Issue Fee Payment Received	⬆	
07-31-2009	Sequence Forwarded to Pubs on Tape	⬆	
07-15-2009	Electronic Review	⬆	
07-14-2009	Mail Notice of Allowance	⬆	
07-09-2009	Document Verification	⬆	
07-09-2009	Notice of Allowance Data Verification Completed	⬆	
07-09-2009	Case Docketed to Examiner in GAU	⬆	
06-17-2009	Information Disclosure Statement considered	⬆	
06-17-2009	Electronic Information Disclosure Statement	⬆	
06-26-2009	Date Forwarded to Examiner	⬆	
06-17-2009	Amendment after Final Rejection	⬆	
06-17-2009	Information Disclosure Statement (IDS) Filed	⬆	
03-18-2009	Electronic Review	⬆	
03-18-2009	Email Notification	⬆	
03-18-2009	Mail Final Rejection (PTOL - 326)	⬆	
03-13-2009	Final Rejection	⬆	
01-26-2009	Date Forwarded to Examiner	⬆	
01-09-2009	Response after Non-Final Action		92
01-09-2009	Request for Extension of Time - Granted		⬆
07-09-2008	Electronic Review		⬆
07-09-2008	Email Notification		⬆
07-09-2008	Mail Non-Final Rejection		⬆
07-03-2008	Non-Final Rejection		
04-18-2008	Information Disclosure Statement considered		
09-01-2005	Information Disclosure Statement considered		
04-18-2008	Information Disclosure Statement (IDS) Filed		

**Exhibit A**

05-01-2008	Date Forwarded to Examiner	
04-18-2008	Response to Election / Restriction Filed	
04-18-2008	Information Disclosure Statement (IDS) Filed	
03-22-2008	Electronic Review	
03-21-2008	Email Notification	
03-19-2008	Mail Restriction Requirement	
03-11-2008	Requirement for Restriction / Election	
01-17-2008	Date Forwarded to Examiner	
01-11-2008	Response to Election / Restriction Filed	
01-11-2008	Request for Extension of Time - Granted	
10-13-2007	Electronic Review	
10-11-2007	Email Notification	
10-11-2007	Mail Restriction Requirement	391
09-27-2007	Requirement for Restriction / Election	⬆
01-19-2006	Oath or Declaration Filed (Including Supplemental)	⬆
01-09-2006	Case Docketed to Examiner in GAU	⬆
01-09-2006	IFW TSS Processing by Tech Center Complete	⬆
12-14-2005	Miscellaneous Incoming Letter	⬆
09-01-2005	Information Disclosure Statement (IDS) Filed	⬆
09-01-2005	Information Disclosure Statement (IDS) Filed	⬆
07-15-2005	Request for Foreign Priority (Priority Papers May Be Included)	⬆
07-15-2005	Request for Foreign Priority (Priority Papers May Be Included)	⬆
07-15-2005	Request for Foreign Priority (Priority Papers May Be Included)	⬆
07-15-2005	Preliminary Amendment	⬆
12-15-2005	Cleared by OIPE CSR	⬆
12-11-2005	Cleared by OIPE CSR	⬆
12-11-2005	Cleared by OIPE CSR	⬆
12-11-2005	Cleared by OIPE CSR	⬆
07-15-2005	371 Completion Date	⬆
12-02-2005	Application Dispatched from OIPE	
12-02-2005	Notice of DO/EO Acceptance Mailed	
07-28-2005	CRF Is Good Technically / Entered Into Database	
07-15-2005	CRF Disk Has Been Received by Preexam / Group / PCT	
07-15-2005	Initial Exam Team nn	

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